UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION)) MDL No. 1456)
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS and 01-CV-339)))
TRIAL OF CLASS 2 AND 3 CLAIMS	- /

MEMORANDUM OF LAW IN SUPPORT OF TRACK 1 DEFENDANTS' POST-TRIAL MOTION FOR JUDGMENT

TABLE OF CONTENTS

			<u>PAGE</u>
TABLE OF	AUTH	ORITIES	ii
ARGUME	NT		1
I.	DEFE	ENDANTS ARE ENTITLED TO JUDGMENT AS TO CLASS 3	1
	A.	Plaintiffs Failed to Prove Unfairness or Deception	1
	B.	Plaintiffs Have Failed to Establish Causation	6
	C.	Class 3's Claims Exceed the Scope of Chapter 93A	8
		No business transactions with Defendants	8
		2. The alleged wrongful conduct did not occur "primarily and substantially within" Massachusetts	9
II.	DEFE	ENDANTS ARE ENTITLED TO JUDGMENT AS TO CLASS 2	12
	A.	Class 2 Suffers from the Same Failures of Proof as Does Class 3	12
	В.	The Court's Construction of the 1997 Medicare Statute Does Not Es Unfairness or Deception Under Chapter 93A	
	C.	There Are Additional Causation Problems With Respect to Class 2	15
	D.	Class 2 Has Failed to Prove Loss	16
III.		SS 2 AND CLASS 3 CLAIMS ARE BARRED BY THE STATUTE TATIONS	
IV.	WOU	AGGREGATE CLASS JUDGMENT FOR DAMAGES JLD VIOLATE DEFENDANTS' RIGHTS AND RULE 23 OF THE ERAL RULES OF CIVIL PROCEDURE	
V.		SS 2 AND 3 CANNOT ESCAPE JUDGMENT AGAINST THEM B	Y 23

TABLE OF AUTHORITIES

<u>Cases</u>

	<u>Page</u>
<u>Ahern v. Scholz,</u> 85 F.3d 774 (1st Cir. 1996)	5
Allapath Servs. Inc. v. Exxon Corp., 333 F.3d 1248 (11th Cir. 2003), aff'g, 157 F. Supp. 2d 1291 (S.D. Fla. 2001)	22
Basic, Inc. v. Levinson, 485 U.S. 224 (1988)	22
Boston Symphony Orchestra, Inc. v. Commercial Union Ins. Co., 545 N.E.2d 1156 (Mass. 1989)	6
Burbridge v. Board of Assessment of Lexington, 11 Mass. App. Ct. 546, 417 N.E.2d 477 (1981)	21
<u>Carroll v. Butterfield Health Care, Inc.</u> , No. 02-4903, 2003 WL 22462604 (N.D. Ill. Oct. 29, 2003)	15
<u>Chervin v. Travelers Ins. Co.,</u> 448 Mass. 95, 858 N.E.2d 746 (2006)	9
Cimino v. Raymark Indus., 151 F.3d 297 (5th Cir. 1998)	22
Commercial Union Ins. Co. v. Seven Provinces Ins. Co., 217 F.3d 33 (1st Cir. 2000)	1,5
<u>Davis v. Dawson, Inc.</u> , 15 F. Supp. 2d 64 (D. Mass. 1998)	1
<u>Dement v. Wylan,</u> No. 00-2241, 2003 Mass. Super. LEXIS 125 (Mass. Super. Ct. Mar. 10, 2003)	18
Duclersaint v. Federal Nat'l Mortgage Assoc., 427 Mass. 809, 696 N.E.2d 536 (1998)	5
<u>Duco Assocs., Inc. v. Lipson,</u> 11 Mass. App. Ct. 935, 416 N.E.2d 555 (1981)	19

Estate of Sarocco v. Gen. Elec. Co.,	
939 F. Supp. 91 (D. Mass. 1996)	21
Ezenia! Inc. v. Datacraft Mexico, S.A., 18 Mass. L. Rep. 533, 2004 Mass. Super. LEXIS 567 (Mass. Super.	Ct. Nov. 23, 2004) . 10,11
First Enter., Ltd. v. Cooper, 425 Mass. 344, 680 N.E.2d 1163 (1997)	8
<u>Friedman v. Jablonski,</u> 371 Mass. 482, 358 N.E.2d 994 (1976)	19
<u>Frullo v. Landenberger,</u> 61 Mass. App. Ct. 814, 814 N.E.2d 1105 (2004)	16
Geo. Knight & Co., Inc. v. Watson Wyatt & Co., 170 F.3d 210 (1st Cir. 1999)	17
Haberman v. Hustler Magazine, Inc., 626 F. Supp. 201 (D. Mass. 1986)	16
Hanson Housing Auth. v. Dryvit Sys., Inc., 29 Mass. App. Ct. 440, 560 N.E.2d 1290 (1990), rev. den., 409 Mass. 1101, 565 N.E.2d. 792 (1991)	20
<u>Hartman v. Moore,</u> 126 S. Ct. 1695 (2006)	15
Hershenow v. Enterprise Rent-A-Car of Boston, Inc., 445 Mass. 790, 840 N.E.2d 526 (2006)	16
<u>In re Int'l Harvester Co.</u> , 104 F.T.C. 949 (1984)	15
Interstate Brands Corp. v. Lily Transp. Corp., 256 F. Supp. 2d 58 (D. Mass. 2003)	6
James L. Minter Ins. Agency Inc. v. Ohio Indem. Co., 112 F.3d 1240 (1st Cir. 1997)	5
John Beaudette, Inc. v. Sentry Ins. A Mut. Co., 94 F. Supp. 2d 77 (D. Mass. 1999)	18,19
Kenda Corp., Inc. v. Pot O'Gold Money Leagues, Inc., 329 F.3d 216 (1st Cir. 2003)	10,11

Kuwaiti Danish Computer Co. v. Digital Equipment Corp., 438 Mass. 459, 781 N.E.2d 787 (2003)	10
Loguidice v. Metro. Life Ins. Co., 336 F.3d 1 (1st Cir. 2003)	18
Maggio v. Gerard Freezer & Ice Co., 824 F.2d 123 (1st Cir. 1987)	21
Makino, U.S.A., Inc. v. Metlife Capital Credit Corp., 25 Mass. App. Ct. 302, 518 N.E.2d 519 (1988)	9
<u>Markarian v. Conn. Mut. Life Ins. Co.,</u> 202 F.R.D. 60 (D. Mass. 2001)	24
Mass. School of Law v. Am. Bar Assoc., 142 F.3d 26 (1st Cir. 1998)	
Mastromatteo v. Mastromatteo, No. 06-1329, 2006 Mass. Super. LEXIS 582 (Mass. Super. Ct. Nov. 22, 2006)	
Mills v. Allegiance Healthcare Corp., 178 F. Supp. 2d 1 (D. Mass. 2001)	
New England Fin. Res., Inc. v. Coulouras, 30 Mass. App. Ct. 140, 566 N.E.2d 1136 (1991)	
Olsen v. Bell Tel. Labs., Inc., 388 Mass. 171, 445 N.E.2d 609 (1983)	
In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005)	
In re Pharm. Indus. Average Wholesale Price Litig., No. 01-12257, 2006 U.S. Dist. LEXIS 80083 (D. Mass. Nov. 2, 2006)	
RGJ Assocs. v. Stainsafe, Inc., 338 F. Supp. 2d 215 (D. Mass. 2004)	
RLI Ins. Co. v. Wood Recycling, Inc., No. Civ. A. 03-10196, 2006 WL 839514 (D. Mass. Mar. 30, 2006)	
Saenger Org. v. Nationwide Ins. Licensing Assocs.,	18

Storage Technology Corp. v. Custom Hardware Engineering & Consulting, Ltd., No. 02-12102, 2006 U.S. Dist. LEXIS 43690 (D. Mass. June 28, 2006)
Straumann Co. v. Lifecore Biomedical Inc., 278 F. Supp. 2d 130 (D. Mass. 2003)
<u>Swanson v. Bankers Life Co.,</u> 389 Mass. 345, 450 N.E.2d 577 (1983)
<u>Szalla v. Locke,</u> 421 Mass. 448, 657 N.E.2d 1267 (1995)
<u>Tagliente v. Himmer,</u> 949 F.2d 1 (1st Cir. 1991)
<u>USM Corp. v. Arthur D. Little Sys., Inc.,</u> 28 Mass. App. Ct. 108, 546 N.E.2d 888 (1989)
United States v. Chemical Found., Inc., 272 U.S. 1 (1926)
United States Postal Service v. Gregory, 534 U.S. 1 (2001)
<u>Whitcomb v. Pension Dev. Co.,</u> 808 F.2d 167 (1st Cir. 1986)
<u>Windham v. Amer. Brands, Inc.,</u> 565 F.2d 59 (4th Cir. 1977)
<u>Wise v. Hubbard,</u> 769 F.2d 1 (1st Cir. 1985)
<u>Zamboni v. Aladan Corp.,</u> 304 F. Supp. 2d 218 (D. Mass. 2004)
STATUTES & RULES
42 U.S.C. §13951
42 U.S.C. §1385l(a)(l)(S)
42 U.S.C. §1395u(o)
42 U.S.C. §1395w-3a(b)(2)(A)

42 U.S.C. §1395w-3a(c)	14
42 U.S.C. §1396r-8	14
42 U.S.C. §1396r-8(b)(3)(A)	14
42 U.S.C. §1396r-8(b)(3)(A)(iii)(I)	14
Attorney General Regulations 940 C.M.R. § 3.16(3)	6
Attorney General Regulations 940 C.M.R. § 3.16(4)	6
Fed. R. Civ. P. 23	22,24
Fed. R. Civ. P. 23(b)(3)	23
Mass. Ann. Laws, Ch. 93A	assim
Mass. Ann. Laws , Ch. 260	17, 21
OTHER AUTHORITIES	
Dwight Golann, et al., "Standards of Conduct Under Chapter 93A: What is a Section 11 Violation?" MULTIPLE DAMAGE CLAIMS IN BUSINESS LITIGATION at 7 (1993)	9
Edward P. Leibensperger & Glenn E. Deegan, "Section 11 of c. 93A: What Must You Satisfy Before You Get to the Eyebrow Test?" MULTIPLE DAMAGE CLAIMS IN BUSINESS LITIGATION at 33-34 (1993)	9
OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003)	13

ARGUMENT

Plaintiffs' claims are governed by the Massachusetts Consumer Protection statute, Ch. 93A. Plaintiffs failed to bear their burden of proof with respect to several elements of Ch. 93A; the insufficiency with respect to any one of these elements independently requires the entry of judgment for Defendants against both Class 2 and Class 3.

I. DEFENDANTS ARE ENTITLED TO JUDGMENT AS TO CLASS 3

A. Plaintiffs Failed to Prove Unfairness or Deception

In order to show deception or unfairness, Plaintiffs must prove that Defendants' conduct attains a "level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce." Commercial Union Ins. Co. v. Seven Provinces Ins. Co., 217 F.3d 33, 40 (1st Cir. 2000) (internal citations omitted). An important consideration in this analysis is what the parties knew or should have known with respect to the conduct at issue. Furthermore, conduct that is consistent with industry standards is not unfair or deceptive under Ch. 93A. See, e.g., USM Corp. v. Arthur D. Little Sys., Inc., 28 Mass. App. Ct. 108, 125, 546 N.E.2d 888, 898 (1989) (affirming judgment that no unfair or deceptive acts occurred when plaintiff was not misled, and when defendant's "financial reporting practices were in conformity with accepted methods within the business community").

¹ <u>See, e.g., Davis v. Dawson, Inc.</u>, 15 F. Supp. 2d 64, 146 (D. Mass. 1998) (Saris, J.) ("In evaluating the unfairness of the objectionable conduct, this court may 'assess the equities between the parties, including what both parties knew or should have known."") (internal citations omitted); <u>Swanson v. Bankers Life Co.</u>, 389 Mass. 345, 349, 450 N.E.2d 577, 580 (1983) ("[A] plaintiff's conduct, his knowledge, and what he reasonably should have known may be factors in determining whether an act or practice is unfair"); <u>New England Fin. Res. Inc. v. Coulouras</u>, 30 Mass. App. Ct. 140, 148, 566 N.E.2d 1136, 1140 (1991) (affirming rejection of Ch. 93A counterclaims based on a finding that "there was no deception—that the defendants, acting under the advice of counsel, knew precisely what they were doing").

Plaintiffs have not demonstrated deception under Ch. 93A because Plaintiffs failed to prove that any third party payer ("TPP") in fact was misled.² It is extraordinary that in this case, where Plaintiffs explicitly alleged deception, no witness testified that he or she was misled in setting reimbursements. To the contrary, for example, Edward S. Curran, the former Director of Pharmacy for the class representative BCBS/MA, testified that it was commonly known in the industry for decades that AWP is not an actual average of wholesale prices. (Track 1 Defendants Joint Findings of Fact ¶ 32 [hereinafter "Defs. FF"]). He also testified that health plans knew by the mid-1980s that AWP bore no predictable relationship to drug acquisition costs due to variable rebates and discounts, the extent of which turned on the degree of therapeutic competition. (Defs. FF ¶¶ 33-35). Indeed, when Curran was employed at BCBS/MA, he knew of acquisition costs of up to 90% below WAC. (Defs. FF ¶ 34). Numerous other BCBS/MA employees also had detailed knowledge regarding AWP. (Defs. FF ¶¶ 36-41). And BCBS/MA was a direct purchaser of the drugs used at its staff model HMO. (Defs. FF ¶¶ 42-46). None of the witnesses who said they believed AWP was an average of transaction prices said that reimbursement rates were based on this misunderstanding or that reimbursement rates would have been different had they known otherwise.

In lieu of direct evidence from payers, Plaintiffs relied on the fundamentally flawed opinion testimony of Dr. Raymond S. Hartman, who opined that payers "expected" that AWPs did not exceed ASPs by more than 30%. (Defs. FF ¶ 74.)³ Initially, Dr. Hartman represented that he would conduct surveys to determine payer expectations. (Defs. FF ¶ 78). He did not do

² No § 9 claim of any insured consumers in Class 3 was presented or tried. The only class representatives who presented evidence at trial were commercial insurers.

 $^{^3}$ Dr. Hartman testified that Medicare had similar expectations, and in his original expert report he used a liability threshold of 30% to establish liability for Class 2. (Defs. FF ¶ 74).

so. (<u>Id.</u>). He did not even talk to any TPPs before arriving at his 30% yardstick. (<u>Id.</u>). Instead, he relied on three surrogates to determine payer expectations: (1) comparator drugs; (2) publicly available information on spreads; and (3) contracts between TPPs and providers. (<u>Id.</u>). None of these surrogates support Dr. Hartman's 30% expectation yardstick.

With respect to the first surrogate—comparator drugs—Dr. Hartman compared the spreads on drugs that did not face competition to the spreads on drugs that did face competition. (Defs. FF ¶ 79). That comparison is not meaningful, however, unless TPPs did not know that discounts increase when there is competition. To the contrary, there is extensive evidence that TPPs did understand that competition leads to discounting. (Defs. FF ¶¶ 31-41, 64, 80-82; DX 1275). Dr. Hartman's first surrogate, therefore, does not work.

Dr. Hartman's second surrogate—publicly available information on spreads—is derived from self-selected reports depicting spreads of 30% or less for certain drugs. (Defs. FF ¶¶ 83, 84). Those same reports also depict spreads in excess of 30% for both single-source and multi-source drugs. (Defs. FF ¶ 84). Indeed, some of the reports depict spreads exceeding 400% in 1992 and 1000% in 1996. (Defs. FF ¶¶ 9, 10, 83, 84; DX 2631). Substantial evidence demonstrates that a number of TPPs, including class representative BCBS/MA, purchased drugs at prices similar to Dr. Hartman's ASPs. (Defs. FF ¶ 46; DX 2001). Accordingly, Dr. Hartman's second surrogate does not work either.

Dr. Hartman's third surrogate—TPP contracts with providers—comes from Dr. Hartman's observation that reimbursement contracts frequently specify a range of AWP plus or minus 15%. Supposedly, this reveals payer expectations with respect to the amount of any spread. (Defs. FF ¶ 86). Significantly, however, Dr. Hartman could not explain how the range of reimbursements translated into an expectation that AWP did not exceed acquisition cost by

more than 30% (<u>Id.</u>), and it is plain that this theory does not work unless TPPs intended to limit provider profits to no more than 30% per drug. The evidence in the case demonstrates, however, that payers do not consider reimbursements on a drug-by-drug basis; rather, they focus on reimbursement levels overall. (Defs. FF ¶ 89). There was also extensive evidence that payers use margins on drugs to attract providers to their networks, encourage treatment outside of the hospital and cross-subsidize underpayment for services, but Dr. Hartman failed to consider these factors in his analysis. (Defs. FF ¶¶ 86-88, 90, 92, 93). Thus, Dr. Hartman's third surrogate also fails.

Furthermore, the evidence contradicts the fundamental premise of Dr. Hartman's theory—that payers had an expectation that AWPs exceeded ASPs by a reasonably predictable amount. One of the key documents that Dr. Hartman relied on for this proposition, a 1992 OIG report, explicitly states that "AWP is not a reliable indicator of the cost of a drug to physicians." (Defs. FF ¶ 7, 83). Even Dr. Hartman conceded that "During the 1990s, the relevant Medicare agencies (HCFA, CMS) were presented with increasingly compelling and consistent information sufficient to make clear that while AWP historically may have reflected provider acquisition cost ... AWP was no longer the reliable benchmark it had been and had been believed to be." (Defs. FF ¶¶ 36, 38, 64, 85). TPP witnesses similarly testified at trial that they did not expect a 30% relationship between AWP and ASP, forcing Dr. Hartman to concede that at least those TPPs' expectations did not fit within his theory. (Defs. FF ¶ 85).

Similarly, Plaintiffs did not establish that Defendants acted unfairly. To state a claim for unfairness, Plaintiffs must prove unconscionable conduct. Mass. School of Law v. Am. Bar Assoc., 142 F.3d 26, 41 (1st Cir. 1998). A defendant that follows standard industry practice is not acting unfairly; accordingly, the mere reporting of AWPs in excess of acquisition cost does

not violate Ch. 93A. AWP is a formulaic mark-up over the manufacturer's undiscounted list price (commonly referred to as "WAC"). This custom and practice in the industry was established many years prior to the class period, and long before AWP was first used as a reimbursement benchmark. See James L. Miniter Ins. Agency Inc. v. Ohio Indem. Co., 112 F.3d 1240, 1251 (1st Cir. 1997) (no unfairness where defendant adhered to industry custom).

Indeed, when HCFA incorporated AWP into a regulation in 1991, and Congress later used it in a statute in 1997, it never occurred to any Defendant that they should change their price reporting practices. (Defs. FF ¶ 14); see Ahern v. Scholz, 85 F.3d 774, 798 (1st Cir. 1996) (unfairness depends on what a party knew and should have known). Dr. Berndt has acknowledged that no single company in the industry could change the way AWPs were calculated and disseminated by industry publications. (Defs. FF ¶ 15 n.1). Indeed, the competitive practices were described by both sides' experts as "normal" and "rational" competitive behavior. (Defs. FF ¶ 82).

The statute requires Plaintiffs to prove that Defendants' conduct was immoral, unethical, oppressive or unscrupulous. Commercial Union Ins. Co., 217 F.3d at 40. A defendant's good faith interpretation of an industry term is "not the stuff of which c. 93A is made" – even if that interpretation is later found to be incorrect. See, e.g., Duclersaint v. Federal Nat'l Mortgage Assoc., 427 Mass. 809, 815, 696 N.E.2d 536, 540 (1998) (finding no 93A violation, even though defendant violated foreclosure statute, because defendant "simply held a different opinion as to the applicability of [the foreclosure statute].")⁴ The record here establishes that the conduct at issue was consistent with standard industry practice.⁵

⁴ <u>See also RLI Ins. Co. v. Wood Recycling, Inc., No. Civ. A. 03-10196, 2006 WL 839514, at *5-6 (D. Mass. Mar. 30, 2006) (finding no liability under 93A § 11 because insurer's interpretation of a policy term, even (...continued)</u>

B. Plaintiffs Have Failed to Establish Causation

Ch. 93A requires proof that Defendants' conduct was a "but for" and "proximate" cause of Plaintiffs' loss. Accordingly, Plaintiffs must show that they would have acted differently "but-for" the allegedly deceptive conduct. Markarian v. Conn. Mut. Life Ins. Co., 202 F.R.D. 60, 68 (D. Mass. 2001). No witness testified that his or her company based reimbursement on a misunderstanding of AWP or that it would have set a different rate if it had known that providers often purchased Defendants' products at substantial discounts.

To the contrary, the evidence shows that BCBS/MA's eyes were wide open—BCBS/MA was well aware of the difference between AWP and ASP; it evaluated and studied the AWP-based reimbursement system; and, most strikingly, concluded that using published AWPs was to its advantage. BCBS/MA considered reforming its reimbursement methods in 2004, but affirmatively elected to continue using AWP rather than shift to an ASP-based reimbursement system for physician-administered drugs. (Defs. FF ¶¶ 47-51). Similarly, BCBS/MA did not

(continued...)

though "absurd" and "unpersuasive," "fell within the realm of the 'plausible,' though ultimately incorrect"); <u>Boston Symphony Orchestra, Inc. v. Comm. Union Ins. Co.</u>, 406 Mass. 7, 13-14, 545 N.E.2d 1156, 1160 (1989) (same); <u>Interstate Brands Corp. v. Lily Transp. Corp.</u>, 256 F. Supp. 2d 58, 61 (D. Mass. 2003) (finding no 93A violation when defendant used "plausible, albeit ultimately unavailing" interpretation of ambiguous contractual term).

⁵ Given the failures of proof, Plaintiffs attempted to circumvent this fundamental requirement of Ch. 93A by contorting Attorney General Regulations 940 C.M.R. § 3.16(4) and § 3.16(3) to allow for a "per se" finding of unfairness or deception. This position is without merit for all the reasons previously stated. Defendants incorporate by reference Defendants' Memorandum of Law in Response to Plaintiffs' Memorandum Regarding Defendants' Per Se Unfair and Deceptive Practices (filed December 11, 2006), Docket No. 3453, which fully explicates the law on this issue. In addition, the record is undisputed: the publishers of the compendia sold that data. Sales of data are not "advertisements" or "advertising" under any of the inapposite materials Plaintiffs cited. Moreover, Plaintiffs acknowledge that even with per se liability, Plaintiffs would still have to establish the remaining elements of Ch. 93A § 11. Plaintiffs would also have to surmount the statute of limitations on their claims. Plaintiffs' Memorandum of Law Regarding Defendants' Per Se Unfair and Deceptive Practices (filed November 27, 2006), Docket No. 3417 at 6.

⁶ Defendants incorporate by reference Track 1 Defendants' Memorandum of Law In Response to the Court's Questions Concerning the Implication of Evidence With Respect to Class 3 Named Representatives for the Remainder of the Class (filed December 15, 2005), Docket No. 3479.

change its reimbursement methodology for its managed Medicare program (called BC 65) to 85% of AWP or to ASP, even though it considered both options. (Defs. FF ¶ 52). Moreover, BCBS/MA is currently extending its usage of AWP-based reimbursement to hospitals in place of a billed charge methodology based on its considered conclusion that an AWP based system is preferable because it saves money and provides enhanced predictability and ease of administration. (Defs. FF ¶¶ 55, 56). BCBS/MA intends to continue transitioning hospitals to AWP as their contracts come up for renewal every year until the transition is complete by 2011. (Defs. FF ¶ 56). The significance of BCBS/MA's actions is highlighted by the evidence that BCBS/MA is the largest payer in Massachusetts and covers almost half the lives in the Commonwealth. (Defs. FF ¶ 30).

The record does not support a different result for Taft Hartley plans represented by BCBS/MA and Pipefitters.⁷ Pipefitters is not only charged with the actual knowledge of its agent, BCBS/MA, ⁸ but it is also bound by its reliance on BCBS/MA. (Defs. FF ¶¶ 31-46). Indeed, by contract, Pipefitters must reimburse for physician administered drugs at the rate determined by BCBS/MA, and Pipefitters relies upon BCBS/MA to achieve the best rates it can. (Defs. FF ¶¶ 68). Moreover, BCBS/MA told Pipefitters that 95% of AWP is the best rate available in the marketplace. (Id.). Even Plaintiffs' counsel conceded that these health plans rely on sophisticated health insurers or benefits consultants in connection with reimbursements. (Defs. FF ¶ 67).

⁷ Defendants incorporate by reference the arguments made in Track 1 Defendants' Memorandum of Law in Response to the Court's Questions Concerning the Implication of Evidence With Respect to Class 3 Named Representatives for the Remainder of the Class (filed December 15, 2006), Docket No. 3479 at 9-14.

⁸ <u>See</u> Track 1 Defendants Memorandum of Law in Support of Their Motion for Summary Judgment With Respect to Class 3 (filed July 14, 2006) at 24.

C. Class 3's Claims Exceed the Scope of Chapter 93A

Chapter 93A, § 11 also requires that the conduct at issue occur "primarily and substantially in the commonwealth" and in the context of a business transaction between Plaintiff and Defendant. The gravamen of these requirements is to limit the application of Massachusetts consumer protection law to conduct that is directed towards Massachusetts because, as this Court has noted, "state consumer protection statutes are designed to protect consumers rather than regulate corporate conduct." In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 83 (D. Mass. 2005) (citing cases) [hereinafter "Class Cert. Opinion"]. 9

1. No business transactions with Defendants

In this case, it is undisputed that no transaction between Plaintiffs and Defendants resulted in any harm. Defendants incorporate by reference the extensive briefing on the business transaction requirement under Ch. 93A, §11.¹⁰ Since the Massachusetts Supreme Judicial Court's ("SJC") holding in Szalla v. Locke, 421 Mass. 448, 657 N.E.2d 1267 (1995), establishing the business transaction requirement, no Massachusetts court has applied § 11 in a case where there was no actual or contemplated business transaction between the plaintiff and

⁹ Furthermore, there is no indication that the Massachusetts Legislature intended Ch. 93A, and it should not be so construed, to apply to matters founded on and involving the doctor-patient relationship and medical prescribing decisions. See <u>First Enterprises Ltd. v. Cooper</u>, 425 Mass. 344, 680 N.E.2d 1163 (1997) (93A does not apply to interaction between lawyer and client).

Transaction Requirement in 11 of Ch. 93A (filed November 6, 2006), Docket No. 3326; Defendants' Memorandum of Law in Reply to Plaintiffs' Response Memorandum Regarding the Transaction Requirement Under Massachusetts General Laws Ch. 93A, § 11 (filed December 1, 2006), Docket No. 3435; Defendants' Opposition to Plaintiffs' Motion for Leave to File a Sur-Reply Opposition Regarding the Transaction Requirement Under Massachusetts General Laws Ch. 93A, §11 (filed December 21, 2006), Docket No. 3498.

the defendant. The Massachusetts SJC reaffirmed this requirement within the past month. Chervin v. Travelers Ins. Co., 448 Mass. 95 112-113, 858 N.E.2d 746 (Mass. 2006). 11

2. The alleged wrongful conduct did not occur "primarily and substantially within" Massachusetts

Jurisdiction under Chapter 93A, § 11 is limited to business transactions within Massachusetts. 12 Section 11 states that:

No action shall be brought or maintained under this section unless the actions and transactions constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred <u>primarily and substantially within the commonwealth</u>.

MASS. ANN. LAWS Ch. 93A, § 11 (emphasis added). This jurisdictional requirement limits the scope of § 11 to unfair or deceptive acts or practices which occurred <u>for the most part</u> within Massachusetts.¹³

This Court's analysis of whether the conduct occurred primarily and substantially within the Commonwealth is governed by the Massachusetts SJC's decision in <u>Kuwaiti Danish</u> Computer Co. v. Digital Equipment Corp., 438 Mass. 459, 473, 781 N.E.2d 787, 799 (2003). In

¹¹ In <u>Chervin</u>, the plaintiff physician asserted a 93A, § 11 claim against an insurance company for malicious prosecution of a subrogation claim against him based on allegedly improper care of one of his patients. Citing <u>Szalla</u>, the SJC affirmed summary judgment against the plaintiff physician on his § 11 claim because the physician could not "establish that he had any relevant business transaction with the defendant which would serve as a predicate for liability under G.L. c. 93A, §§ 2 and 11." <u>Chervin v. Travelers Ins. Co.</u>, 448 Mass. 95, 112-113, 858 N.E.2d 746 (2006); <u>see also Mastromatteo v. Mastromatteo</u>, No. 06-1329C, 2006 Mass. Super. LEXIS 582, at *9 (Mass. Super. Ct. Nov. 22, 2006) (dismissing 93A claims because plaintiff "has failed to allege any commercial activity that occurred between himself and [defendants]") (citing Szalla).

¹² See Dwight Golann, et al., "Standards of Conduct Under Chapter 93A: What is a Section 11 Violation?" MULTIPLE DAMAGE CLAIMS IN BUSINESS LITIGATION at 7 (1993) ("[A]s a result of a series of amendments, Section 4 and Section 9 plaintiffs can now sue over illegal practices committed entirely outside Massachusetts, if they harm consumers within the Commonwealth. By contrast, Section 11 plaintiffs can sue only over improper acts and practices which occur "primarily and substantially" within the state.").

The jurisdictional requirements of Ch. 93A, § 11 have undergone a series of amendments since its inception in 1967. <u>See</u> Edward P. Leibensperger & Glenn E. Deegan, "Section 11 of c. 93A: What Must You Satisfy Before You Get to the Eyebrow Test?" MULTIPLE DAMAGE CLAIMS IN BUSINESS LITIGATION at 33-34 (1993); <u>see also Makino, U.S.A., Inc. v. Metlife Capital Credit Corp.</u>, 25 Mass. App. Ct. 302, 309 n.4, 518 N.E.2d 519, 523 n.4 (1988).

<u>Kuwaiti</u>, the SJC adopted a "center of gravity" test, in which the "judge should, after making findings of fact, and after considering those findings in the context of the entire § 11 claim, determine whether the center of gravity of the circumstances that give rise to the claim is primarily and substantially within the Commonwealth." <u>Kuwaiti</u>, 438 Mass. at 473; <u>see also Kenda Corp.</u>, Inc. v. Pot O'Gold Money Leagues, Inc., 329 F.3d 216, 235 (1st Cir. 2003) (applying center of gravity test); <u>RGJ Assocs. v. Stainsafe</u>, Inc., 338 F. Supp. 2d 215, 233-34 (D. Mass. 2004) (same).

Kuwaiti placed one concrete limitation on the application of the test: the analysis must only consider the alleged wrongdoer's actionable conduct, as opposed to its benign conduct. "Contacts with Massachusetts that were neither unfair nor deceptive do not play a part in assessing whether the misconduct occurred primarily and substantially in Massachusetts." RGJ Assocs., 338 F. Supp. 2d at 233-34; Kuwaiti, 438 Mass. 474-75; Ezenia! Inc. v. Datacraft Mexico, S.A., 18 Mass. L. Rep. 533, 2004 Mass. Super. LEXIS 567 at *7 (Mass. Super. Ct. Nov. 23, 2004). Accordingly, courts applying Kuwaiti place great weight on the location of the defendant's allegedly deceptive statements and the place that an allegedly deceptive scheme was concocted. See, e.g., Ezenia! Inc., 2004 Mass. Super. LEXIS 567, at *7-8.14 Furthermore, under Kuwaiti, where, as here, defendants' allegedly deceptive or unfair conduct took place outside Massachusetts, the fact of a loss in Massachusetts does not control. See e.g., Storage

_

¹⁴ <u>See also, Kenda Corp., Inc.</u>, 329 F.3d at 235 (affirming lower court's grant of summary judgment for defendants because the two key meetings during which the alleged misrepresentations occurred were in Michigan); <u>Kuwaiti</u>, 434 Mass. 475 (concluding that nearly all of the conduct that could be said to be unfair or deceptive occurred in Washington, D.C.).

Technology Corp. v. Custom Hardware Engineering & Consulting, Ltd., No. 02-12102, 2006 U.S. Dist. LEXIS 43690 (D. Mass. June 28, 2006). 15

The allegedly actionable conduct did not occur "primarily and substantially within" Massachusetts. The Defendants' supposedly fraudulent AWPs emanated from each Defendant's headquarters—all located outside of Massachusetts—and were sent to independent publishing companies—also located outside of Massachusetts. (Defendant AstraZeneca's FF ¶ 13 [hereinafter "AZ FF"]). From that point, the compendia sold the published AWP data in both hardcopy and electronic form to various, geographically disparate customers. Moreover, to the extent Plaintiffs argue that the conduct at issue is not just publication of AWPs, but a sales strategy relating to "marketing the spread," any such strategy did not occur "primarily and substantially" in Massachusetts. In fact, there is no evidence regarding Defendants' marketing programs in Massachusetts. The only evidence concerning Defendants' marketing practices relate to their national programs or to geographies outside of Massachusetts. See Kenda Corp., 329 F.3d at 236 (noting that the activities that occurred outside Massachusetts were "ancillary"

¹⁵ See also, Ezenia! Inc., 2004 Mass. Super. LEXIS 567; <u>Kenda Corp. Inc.</u>, 329 F.3d at 235-36.

Massachusetts. In the class certification decision issued on August 16, 2005, this Court confronted this very question when analyzing the choice of law issue. Class Cert. Opinion, 230 F.R.D. at 82-83. The Court acknowledged that "the defendants made the alleged misrepresentations in the states of their principal places of business when sending AWPs to publishers." Id. at 83. Plaintiffs also recognize that the core conduct at issue in this case occurred outside of Massachusetts. At the class certification stage, Plaintiffs argued that individual legal issues did not predominate "because this Court need only apply the laws of the states where the Track One defendants have their principal places of business, where they made the misrepresentations as to drug prices." Id. at 82 (emphasis added). In fact, Plaintiffs have openly admitted their reliance on conduct that occurred outside of Massachusetts. In Plaintiffs' Response to Defendant's Motion in Limine on the Guilty Plea, Plaintiffs asserted the relevance of non-Massachusetts conduct, stating that "this Court did not restrict this trial to conduct that occurred in Massachusetts; it restricted it to injury that occurred in Massachusetts. See Pls.' Response to Def.'s Mot. In Limine On Guilty Plea at 8 (filed Oct. 16, 2006), Docket No. 3215 (emphasis in original).

 $^{^{17}}$ Strikingly, there is no evidence in the record that BCBS/MA or Pipefitters ever purchased published AWP data.

to those that occurred out of state); <u>Straumann Co. v. Lifecore Biomedical Inc.</u>, 278 F. Supp. 2d 130, 140 (D. Mass. 2003) (holding that "because only 2.3% of [defendant's] sales occurred within Massachusetts Straumann cannot show that any alleged act of unfair competition occurred 'primarily and substantially in Massachusetts'").

Application of Ch. 93A to these facts would eviscerate this jurisdictional limitation and may have significant collateral consequences for Class 1 claims under the laws of the over 40 states which the Court has not yet examined.¹⁸

II. DEFENDANTS ARE ENTITLED TO JUDGMENT AS TO CLASS 2

A. Class 2 Suffers From the Same Failures of Proof As Does Class 3

The legal principles and failure of proof set forth above as to Class 3 (which Defendants incorporate by reference) also compels judgment in favor of Defendants with respect to the claims of Class 2. In particular: (a) Plaintiffs have not proven unfairness or deception; (b) Plaintiffs have not proven causation; (c) there was no business transaction between the two Medi-gap insurers and Defendants; and (d) the allegedly actionable conduct did not occur primarily and substantially within Massachusetts. Below, Defendants set forth additional reasons, unique to Class 2, which also entitle Defendants to judgment.

B. The Court's Construction of the 1997 Medicare Statute Does Not Establish Unfairness or Deception Under Chapter 93A

Medi-gap Plaintiffs cannot salvage their claim by resorting to a <u>per se</u> theory of unfairness or deception because the Attorney General regulations the Plaintiffs ask this Court to

 $^{^{18}}$ The "primarily and substantially" requirement applies only to claims brought under 93A, \S 11. MASS. Ann. Laws Ch. 93A, \S 11.

apply are inapposite.¹⁹ Defendants refer to and incorporate the briefing explicating the <u>per se</u> theory and its inapplicability, and make the following additional points.²⁰

Plaintiffs' <u>per se</u> theory, to the extent it seeks to conflate the Court's "plain meaning" construction of the 1997 statute with a finding of unfairness or deception, is entirely misplaced. A necessary—yet entirely unfounded—corollary of such a theory would be that the Secretary of CMS improperly exercised her power to set Medicare reimbursements at levels that were incorrect, and did so for millions of transactions. Were the Court to so rule, these unauthorized determinations by the Secretary would provide a complete defense to Defendants because the record is undisputed that Medicare-related reimbursements were set by the Secretary and the Secretary alone.

Defendants also note that this Court's ruling that the term "average wholesale price" be construed in accordance with plain meaning neither cures the failure of proof with respect to unfairness or deception nor controls the outcome of this case. <u>In re Pharm. Indus. Average Wholesale Price Litig.</u>, No. 01-12257, 2006 U.S. Dist. LEXIS 80083, at *37 (D. Mass. Nov. 2, 2006). The 1997 statute²¹ does not require drug manufacturers to do (or not do) anything. The statute provided:

Defendants also note that Plaintiffs' reference to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003), is misplaced and unavailing. The Guidance, which was published in 2003, explicitly states that it does not create law or legal obligations and is "not intended to imply that the practice or activity [described] is necessarily illegal . . . or that it may not have a valid or lawful purpose underlying it." (Defs. FF ¶ 29 n.3). Track 1 Defendants' Joint Memorandum In Opposition to Plaintiffs' Motion for Partial Summary Judgment Against All Track 1 Defendants (filed Apr. 7, 2006), Docket No. 2378 at 9-11.

Defendants incorporate by reference Defendants' Memorandum of Law in Response to Plaintiffs' Memorandum Regarding Defendants' <u>Per Se</u> Unfair and Deceptive Practices (filed December 11, 2006), Docket No. 3453.

²¹ The "statute"—the Balanced Budget Act of 1997—is 507 pages long. We assume the Court meant the one paragraph section in that statute.

If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to 95 percent of the average wholesale price.

42 U.S.C. § 1395u(o). All this section did was describe "the amount payable." An entirely different section, 42 U.S.C. § 1395l, entitled "Payment of Benefits," provided:

[T]here shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under [Medicare Part B] . . . amounts equal to . . . (S) with respect to drugs and biologicals . . . the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1395u(o) of this title.

42 U.S.C. § 1385l(a)(l)(S). There is no statutory command in either section dictating that drug manufacturers' conduct must conform to some prescribed norm. There is no requirement that drug manufacturers report or refrain from reporting anything, in any particular way, to any particular entity. It is clear that when Congress intends to impose obligations on manufacturers, it knows how to do so. See 42 U.S.C. § 1396r-8 (Best Price provision). For example, when Congress passed the Medicare Modernization Act ("MMA") in 2003, it provided a definition of "average sales price," 42 U.S.C. § 1395w-3a(c), and explicitly required each manufacturer with a Best Price agreement to "report to the Secretary," the "average sales price" and "the total number of units specified under [42 U.S.C. § 1396r-8(b)(3)(A)]." 42 U.S.C. § 1395w-3a(b)(2)(A); 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(I). Thus, when Congress chooses to impose affirmative obligations on parties, it does so unequivocally. In contrast, the 1997 statute does not compel or prohibit any conduct on the part of drug manufacturers. Accordingly, 42 U.S.C. § 1395u(o) and

42 U.S.C. § 1395l impose no obligations upon Defendants and therefore the 1997 statute cannot support Plaintiffs' <u>per se</u> theory.²²

C. There Are Additional Causation Problems With Respect to Class 2

Plaintiffs have failed to prove that Defendants' conduct caused a loss of money or property. It was CMS, not Defendants, that determined the amount that Medi-gap insurers paid for Part B drugs.²³ BCBS/MA and Sheet Metal Workers ("SMW") made Medi-gap payments in accordance with the amounts determined by CMS and recorded on their beneficiaries' Explanation of Medicare Benefits ("EOMBs"). (Defs. FF ¶ 61 n.7). In fact, BCBS/MA testified that published AWPs were irrelevant to BCBS/MA's administration of the Medi-gap plans. (Id.). Thus, the record evidence establishes that BCBS/MA's and Pipefitters' Medi-gap reimbursements resulted from CMS's actions (calculations), not Defendants' conduct.²⁴

Moreover, the record provides no basis for any purported violation of "public policy" under the unfairness test. As the FTC has held, there can be no liability based on a violation of public policy when such a policy is not "clear and well-established." In re Int'l Harvester Co., 104 F.T.C. 949, 1072 (1984) (stating that such a policy must be "one that is widely shared, and not the isolated decision of a single state or a single court"). Plaintiffs have not proven that there was a "clear and well established" definition of AWP as an actual average of wholesale prices at any time during the class period, much less that this definition imposed obligations on drug manufacturers. See Carroll v. Butterfield Health Care, Inc., No. 02-4093, 2003 WL 22462604, at *3 (N.D. Ill. Oct. 29, 2003) (rejecting consumer protection claim based on public policy prong of unfairness test, when—even though defendants violated provision in the Medicaid Act—public policy was not violated because "the Medicaid Act does not provide a private of action and because Congress did not create a standard of conduct, which if breached gave rise to any claim").

Plaintiffs did not offer any evidence of the basis on which CMS (or the carrier(s) covering Massachusetts) determined the reimbursement amounts. Moreover, Medi-gap insurers did not prove that the amounts they paid were wrong. Federal law charges CMS to determine the amount that must be paid from the Medicare Trust Fund to providers. The "presumption of regularity," a well established and often applied legal doctrine, demands that "in the absence of clear evidence to the contrary, courts presume that [public officers] have properly discharged of their official duties." <u>United States v. Chemical Found.</u>, 272 U.S. 1, 14-15 (1926); <u>see also United States Postal Service v. Gregory</u>, 534 U.S. 1, 10 (2001); <u>Hartman v. Moore</u>, 126 S. Ct. 1695 (2006) (Supreme Court upheld continued vitality of doctrine in a private damages action). Accordingly there is no basis upon which this Court could find a causal link between Defendants' conduct and CMS's reimbursement determinations.

²⁴ In fact, Plaintiffs did not prove what the CMS AWPs were, let alone how CMS obtained the AWPs it used. Furthermore, Plaintiffs cannot prevail on an "indirect causation" theory because the federal government intermediary was not deceived. <u>See</u> Memorandum of Law in Support of Track 1 Defendants' Joint Motion for Summary Judgment (Class 1 & 2) (filed Mar. 15, 2006) at 16-22; (Defs. FF ¶ 6-8, 12, 17).

In addition, Plaintiffs failed to prove that, in the absence of the alleged wrongful conduct, Medi-gap payments would have been any less than what they were. There was widespread agreement that, if reimbursement levels for drugs had been reduced, it would have been necessary for Medicare to increase the reimbursement for the service of administering the drug. (Defs. FF ¶ 90, 91 n.11). Plaintiffs' counsel directed their expert, Dr. Hartman, not to consider this in his analysis. (Defs. FF ¶ 86). Defendants' experts, Dr. Gregory K. Bell and Dr. Eric M. Gaier, both concluded that there is no reason to believe that total reimbursements would have been any lower in the absence of the alleged wrongful conduct. (Defs. FF ¶ 88-90). Although Plaintiffs' expert, Dr. Meredith Rosenthal, suggested that the MMA demonstrated that there would have been a cost savings if AWPs had been within 106% of ASPs, the evidence of any actual savings was at best inconclusive. (Defs. FF ¶ 25-27).

D. Class 2 Has Failed to Prove Loss

Evidence of loss is an essential element of Ch. 93A. See, e.g., Hershenow v. Enterprise Rent-A-Car of Boston, Inc., 445 Mass. 790, 801, 840 N.E.2d 526, 535 (2006) (finding plaintiffs could not recover under Ch. 93A even though defendant's conduct was deceptive because plaintiffs did not show the conduct caused a loss). Under § 11, Plaintiffs must prove that they suffered a loss of "money or property" as a result of Defendants' conduct. Frullo v. Landenberger, 61 Mass. App. Ct. 814, 823, 814 N.E.2d 1105, 1113 (2004); Haberman v. Hustler Magazine, Inc., 626 F. Supp. 201, 214 n.5 (D. Mass. 1986).

The record evidence as to BCBS/MA's premium-setting process for its Medi-gap policies shows no "loss." BCBS/MA projects its drug costs forward as part of its premium calculation

²⁵ Section 11's requirement that plaintiff suffer a loss of "money or property" is distinguished from § 9, which only requires an "injury." MASS. ANN. LAWS Ch. 93A, § 11.

process with the aim of recovering those amounts. (Defs. FF ¶¶ 57, 58). As such, BCBS/MA passes on any costs incurred through premiums. Indeed, BCBS/MA actually profits—rather than suffers a loss—as a result of higher drug costs because it calculates a "contribution to reserves"—its margin above costs—as a percentage of benefits costs and then provides for recovering that amount though its premium calculations. ²⁶ (Defs. FF ¶ 59).

Finally, Plaintiffs cannot connect an alleged loss with any specific manufacturer in relation to multi-source or generic drugs. BCBS/MA conceded that it is impossible to identify from a J-code which manufacturer sold a generic or multi-source drug used with any particular patient. (Defendant Schering-Plough Corp. and Warrick Pharm. Corp. FF ¶ 90). Nor can Plaintiffs' claims relating to multi-source drugs be revived on a theory of "market share liability." Aside from the fact that Plaintiffs submitted no evidence of what the market share of any particular multi-source drug was, this legal theory has no support in Massachusetts law, as this Court previously concluded in Mills v. Allegiance Healthcare Corp., 178 F. Supp. 2d 1, 9 (D. Mass. 2001).

III. CLASS 2 AND CLASS 3 CLAIMS ARE BARRED BY THE STATUTE OF LIMITATIONS

The Class 2 and 3 representatives' claims are barred by the four-year statute of limitations applicable to Ch. 93A claims. MASS. ANN. LAWS Ch. 260, § 5A.

Plaintiffs' claim accrued when, "in the exercise of reasonable diligence, [they] should have known the factual basis of the cause of action." Geo. Knight & Co., Inc. v. Watson Wyatt

²⁶ To the extent that premiums were insufficient in any year to recover the projected amounts, that was not caused by Defendants. Rather, it was because BCBS/MA made a strategic election to avoid seeking the rate increase it knew it needed in order to avoid triggering a regulatory rate hearing, which would result in its files being opened up to review by the Massachusetts Attorney General, the Department of Insurance, and the public. (Defs. FF ¶ 61).

& Co., 170 F.3d 210, 213 (1st Cir. 1999). The evidence is overwhelming that by 1996, at the very latest, any Medi-gap or private insurer knew or, at a minimum, should have known that AWP did not equal ASP and that discounts were widely available to customers of Part B drugs. (Defs. FF ¶ 1-10, 32-36, 38, 41, 100-101). Plaintiffs' expert, Dr. Rosenthal, conceded this point. (Defs. FF ¶ 1, 76, 101). So too did employees of BCBS/MA, who testified that this was common knowledge by the mid-1980s among all payers. (Defs. FF ¶ 31-36, 38, 41-42). Moreover, information that AWP did not equal ASP was detailed in a steady stream of government issued documents as well as in public litigations, in the press, and even in a letter from a prominent relator in qui tam cases to the Administrator of CMS himself. (Defs. FF ¶ 3, 7-10, 18). Accordingly, Plaintiffs had at the latest until January 1, 2001 to bring their claim. The first Complaint was filed, however, in December 2001, at least five years after the action accrued. Plaintiffs' claims are therefore barred.²⁷

Furthermore, there is no basis to toll the statute of limitations. Plaintiffs ask this Court to excuse their delay by application of the "discovery rule." Under the discovery rule, the statute of limitations may be tolled under three circumstances: where a misrepresentation concerns a fact that was "inherently unknowable" to the injured party; where the defendant breached some duty of disclosure; or where the defendant concealed the existence of a cause of action through some affirmative act done with the intent to deceive. Loguidice v. Metro. Life Ins. Co., 336 F.3d 1, 6 (1st Cir. 2003).

²⁷ Given the state of the record, who bears the burden of proof on this issue is inconsequential. We note, however, that in these circumstances, it is Plaintiffs who bear the burden of proof. <u>John Beaudette, Inc. v. Sentry Ins. A Mut. Co.</u>, 94 F. Supp. 2d 77, 111 n.40 (D. Mass. 1999) (Bowler, M.J.) (holding that plaintiff bears the burden of presenting evidence to overcome a statute of limitations bar); <u>see also Saenger Org. v. Nationwide Ins. Licensing Assocs.</u>, 119 F.3d 55, 65 (1st Cir. 1997); <u>Dement v. Wylan</u>, No. 00-2241, 2003 Mass. Super. LEXIS 125, *8 (Mass. Super. Ct. Mar. 10, 2003).

In order to show that a fact leading to the discovery of the alleged misrepresentation was "inherently unknowable," Class 2 and Class 3 have the burden to establish that each could not have uncovered the facts leading to the discovery of their claim through the exercise of such diligence. Tagliente v. Himmer, 949 F.2d 1, 5 (1st Cir. 1991); see also John Beaudette, Inc. v. Sentry Ins. A Mut. Co., 94 F. Supp. 2d 77, 111 n.40 (D. Mass. 1999) (Bowler, M.J.). Thus, if the facts disclosing the fraud are publicly available, a plaintiff will be charged with knowledge of those facts. Wise v. Hubbard, 769 F.2d 1, 2-3 (1st Cir. 1985) ("Under Massachusetts law, a fact is not inherently unknowable when it is a matter discoverable by examination of public records."). 28

As stated, there can be no doubt that these insurers, in the exercise of reasonable diligence, should have known that AWP bore no predictable relationship to acquisition cost and could exceed acquisition cost by more than 30% more than four years prior to the filing of the Complaint.²⁹ (Defs. FF ¶¶ 1-10, 32-36, 38, 41, 100-101). The record in this case is replete with evidence from the public record that it was well-known prior to 1997 that AWP bore no relationship to actual acquisition costs. (Id.). Because this information was available, these insurers cannot show that any lack of knowledge was reasonable, and the discovery rule does not apply. Where the plaintiff "had the means at its disposal to learn" of the facts that serve as a

²⁸ <u>Accord Friedman v. Jablonski</u>, 371 Mass. 482, 486, 358 N.E.2d 994, 997 (1976); <u>Duco Assocs., Inc. v. Lipson</u>, 11 Mass. App. Ct. 935, 935, 416 N.E.2d 555, 556 (1981).

Any claim that the insurers lacked knowledge about the extent of their injury—such as ignorance of "mega-spreads"—is unavailing as a matter of law. The Massachusetts SJC long ago "rejected the notion that knowledge of the extent of an injury should control accrual of a cause of action for statute of limitations purposes." Whitcomb v. Pension Dev. Co., 808 F.2d 167, 170 (1st Cir. 1986); see also Zamboni v. Aladan Corp., 304 F. Supp. 2d 218, 224 (D. Mass. 2004) (stating that claim accrues "even if the plaintiff does not apprehend the full extent or nature of the injury"); Olsen v. Bell Tel. Labs., Inc., 388 Mass. 171, 175, 445 N.E.2d 609, 612 (1983) ("If knowledge of the extent of injury were to control the accrual of a cause of action, the fixed time period of statutes of limitations effectively would be destroyed.")

basis for his claim, the claim is not "unknowable." <u>Hanson Housing Auth. v. Dryvit Sys., Inc.</u>, 29 Mass. App. Ct. 440, 443, 560 N.E.2d 1290, 1292-93 (1990), <u>rev. den.</u>, 409 Mass. 1101, 565 N.E.2d. 792 (1991).

For example, the author of the Barron's article was able to conduct his own survey of actual acquisition costs, examining the top 20 Medicare drugs, which accounted for approximately 70% of Medicare's drug spending. (See Defs. FF ¶ 9). To do this, he collected quotes or price lists from leading wholesalers specializing in sales to physicians, home health firms, nursing homes and hospitals.³⁰ The insurance company Plaintiffs have not proven why they could not have conducted a similar inquiry themselves. These Plaintiff TPPs could have similarly requested invoices from physicians in order to determine the relationship between AWP and actual acquisition cost had they chosen to do so. Furthermore, many TPPs in Massachusetts were in a position to acquire knowledge regarding acquisition costs through other business ventures, including their ownership of Staff Model HMOs. (Defs. FF ¶ 42, 63) In addition, drug-specific data reflecting deep discounts to providers was publicly available for purchase from IMS, a well-known third-party data provider. (AZ FF ¶ 68-69). Indeed, the record establishes not only that these TPPs should have known that physician-administered drugs were available at deep discounts off of AWP, but that they had actual knowledge of this fact throughout the class period by virtue of their own purchases of these drugs at such discounts and their own contracts with manufacturers making these drugs available for purchase at these discounted levels. (Defs. FF ¶¶ 42, 43, 46, 63).

 $^{^{30}}$ $\underline{\text{Id.}}$ The Barron's article also specifically discussed the alleged practice of "marketing the spread." $\underline{\text{Id.}}$

Finally, these Plaintiff TPPs have not shown that any act of fraudulent concealment by Defendants tolled the statute of limitations. Even if the Court were to find that Defendants had committed acts of concealment that were fraudulent.³¹ for the statute to be tolled under MASS. ANN. LAWS. Ch. 260, § 12, Defendants' conduct must have prevented Plaintiffs from discovering their causes of action. Maggio v. Gerard Freezer & Ice Co., 824 F.2d 123, 130-31 (1st Cir. 1987) ("Section 12 tolls the statute of limitations only if the wrongdoer ... keeps from the person injured knowledge of the facts giving rise to a cause of action and the means of acquiring knowledge of such facts"); Wise, 769 F.2d at 3-4. The estoppel provision of Ch. 260 § 12 "is generally not available where the plaintiff is capable of discovering the facts allegedly concealed." Wise, 769 F.2d at 4 (quoting Burbridge v. Board of Assessment of Lexington, 11 Mass. App. Ct. 546, 550, 417 N.E.2d 477, 480 (1981)). Defendants did nothing to prevent Massachusetts payers from discovering the truth about the relationship between AWP and acquisition costs. Indeed, the publicly available reports and information relating to providers' acquisition costs preclude any claim by Plaintiffs that they diligently pursued their claim. Here, Plaintiffs were not only capable of discovering the facts underlying their claims, they in fact did discover them.³²

³¹ The acts on which Plaintiffs rely consist primarily of Defendants keeping their prices to customers confidential, a normal business practice. Similarly, the government advocacy of which Plaintiffs complain cannot, as a matter of law, constitute fraudulent concealment. See Estate of Sarocco v. Gen. Elec. Co., 939 F. Supp. 91, 97 (D. Mass. 1996).

³² In the alternative, although Defendants argue that Plaintiffs' claims are time-barred in their entirety, should this Court find otherwise (contrary to record evidence), Defendants argue that at a minimum Plaintiffs' claims which accrued more than four years prior to the filing of the Complaint are barred. Accordingly, all claims which predate December 1997 are barred.

Furthermore, as described supra at 2-3, 6-7, Plaintiffs cannot show unfairness, deception or causation after they have become aware of the allegedly deceptive conduct. Therefore, under the law of causation, Plaintiffs' claims are barred in their entirety from the point of knowledge forward. Thus, Plaintiffs are not entitled to any (...continued)

IV. AN AGGREGATE CLASS JUDGMENT FOR DAMAGES WOULD VIOLATE DEFENDANTS' RIGHTS AND RULE 23 OF THE FEDERAL RULES OF CIVIL PROCEDURE

Plaintiffs ask the Court to enter an aggregate monetary class judgment in favor of Class 2 and Class 3 against each sub-class Defendant. The Court would violate Defendants' rights and Rule 23 if it purported to require Defendants to make damage payments on this evidentiary record in light of Plaintiffs' substantial failure of proof on damages. See e.g., Basic, Inc. v. Levinson, 485 U.S. 224, 248-49 (1988) (in fraud-on-the-market class action, defendant has the right to challenge each class member's assertion of an element of such a claim); Allapath Servs., Inc. v. Exxon Corp., 333 F.3d 1248, 1258 (11th Cir. 2003) (no aggregate class damage), aff'g, 157 F. Supp. 2d 1291, 1299 (S.D. Fla. 2001) (refusal to enter aggregate judgment for class); Windham v. Amer. Brands, Inc., 565 F.2d 59 (4th Cir. 1977); see also, e.g., Cimino v. Raymark Indus., 151 F.3d 297, 312 (5th Cir. 1998) (Rule 23(b)(3) does not change elements that each class member must establish). Even after the close of the trial record, the very existence of any "loss" by any of these insurers remains unsubstantiated.

Plaintiffs relied on Dr. Hartman for their damage calculation, but there were a number of gaping holes in his analysis. There was extensive testimony that, in a but-for world in which reimbursement for drugs was reduced, the reimbursement for services would have to be increased, but Dr. Hartman did not take that into account in his analysis because Plaintiffs' counsel directed him not to. (Defs. FF ¶ 86). Dr. Hartman also assumed that all reimbursements are based on AWP, even though there was evidence that a substantial percentage are not, and that

(continued...)

damages they claim arose subsequent to the filing of the original Complaint in December 2001, as it is beyond dispute that Plaintiffs were aware of the alleged misconduct once the Complaint was filed.

percentage varies from payer to payer. (Defs. FF ¶¶ 96-99). As a result, Dr. Hartman's damage calculations are off by an unknown—but significant—amount.³³

Moreover, the Court has no information whatsoever regarding the number of "Class 3 insureds" who may be willing to come forward ("Class 3" counsel was unable to find even one);³⁴ in fact, the Court has no information about whether and how many Class 3 insureds may be able to prove (i.e., present documentation) that payments were made to a physician based on published AWP, were they to come forward.³⁵ Even Plaintiffs' expert admitted that not all doctors were reimbursed based on AWP. (Defs. FF ¶ 98). Requiring Defendants to pay "aggregate" class damages would be a guess buttressed by intuition, without foundation in the record, in derogation of Rule 23 and in violation of Defendants' rights.³⁶

V. CLASSES 2 AND 3 CANNOT ESCAPE JUDGMENT AGAINST THEM BY CARVING OUT THE CLASS REPRESENTATIVES

Defendants are entitled to judgment against all TPPs in both Class 2 and Class 3.

Defendants refer to their extensive briefing which explains that the TPP class representatives are

³³ <u>See</u> Track 1 Defendants Memorandum in Support of Their Motion to Strike the Expert Testimony Dr. Raymond S. Hartman (filed January 19, 2006).

³⁴ The "Class 3" counsel's proffer at trial of two insureds from Illinois insured by an Illinois insurance company underscores this point.

³⁵ Counsel argued that many doctors (oncologists) do not bill for or try to collect a "co-pay" (Motion Hearing, Jan. 19, 2006 Tr. at 64), which the Court must presume applies now. Therefore, many "Class 3 insureds" may have not paid anything at all. There is also the issue of deaths of "Class 3 insureds" and who might now be legally entitled to act on that claim.

³⁶ Plaintiffs' damages claim is also limited, if not barred, by their failure to mitigate damages by continuing to use AWP as a reimbursement benchmark while armed with substantial knowledge that AWP was not equal to ASP. Defendants incorporate by reference Track 1 Defendants Memorandum of Law in Support of Their Motion for Summary Judgment With Respect to Class 3 (filed July 14, 2006) at 41.

typical of the class, and demonstrates that the evidence adduced at trial demands judgment in favor of Defendants.³⁷

Moreover, should the Court determine that the evidence at trial indicates that differences in sophistication and knowledge are significant, it would be inappropriate for this Court to reconfigure the class by creating subclasses along a subjective spectrum from knowledge to "babes in the woods." (See Defs. FF ¶ 67). Federal Rule of Civil Procedure 23 requires that a court should not certify a class unless "questions of law or fact common to the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." FED. R. CIV. P. 23. As many courts have noted, where a key element to liability involves the sophistication and knowledge of each class member, individual issues predominate and preclude class certification. Markarian, 202 F.R.D. at 69 (refusing to certify a class under 93A because individual issues of causation predominate where the "total mix of information" available to each class member was "distinctive, if not unique" and because "question of causation must be decided with regard to each purchaser in the context of the particular information" purchaser had). In fact, the need for such a project exposes Plaintiffs' failure to meet Rule 23's requirements, which are aimed at preventing actions necessitating individual inquiries from reaching this stage of proceedings. At this point, the only alternative to granting judgment in favor of Defendants as to the class claims would be to do so against the named representatives and simultaneously decertify Class 2 and 3.

³⁷ Defendants incorporate by reference the arguments made in Track 1 Defendants' Memorandum of Law in Response to the Court's Questions Concerning the Implication of Evidence With Respect to Class 3 Named Representatives for the Remainder of the Class (filed December 15, 2006), Docket No. 3479 at 9-14.

Respectfully submitted,

THE FOLLOWING TRACK 1 DEFENDANTS

By: /s/ Katherine B. Schmeckpeper
Nicholas C. Theodorou (BBO # 496730)
Michael P. Boudett (BBO # 558757)
Katherine B. Schmeckpeper (BBO # 663200)
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02110

D. Scott Wise Michael Flynn Kimberley Harris Davis Polk & Wardwell 450 Lexington Avenue New York, NY 10017

Attorneys for AstraZeneca Pharmaceuticals LP

Steven M. Edwards Lyndon M. Tretter Hogan & Hartson, LLP 875 Third Avenue, Suite 2600 New York, NY 10022

Attorneys for the Bristol-Myers Squibb Co. and Oncology Therapeutics Network Corp.

William F. Cavanaugh, Jr. Andrew D. Schau Erik Haas Patterson, Belknap, Webb & Tyler LLP 1133 Avenue of the Americas New York, NY 10036-6710

Attorneys for the Johnson & Johnson Defendants

John T. Montgomery (BBO #352220) Steven A. Kaufman (BBO #262230) Eric P. Christofferson (BBO #654087) Ropes & Gray LLP One International Place Boston, MA 02110

Attorneys for Schering-Plough Corp. and Warrick Pharmaceuticals Corp.

Dated: January 19, 2007

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on January 19, 2007 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper

Katherine B. Schmeckpeper